INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Application Number 10561033 Filing Date 2005-12-16 First Named Inventor Leifeng Cheng Art Unit 1624 Examiner Name Zachary C. Tucker Attorney Docket Number 133087.09601 101119-1P US

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| Examiner Initial* | Cite No | Patent Number | Kind Code ¹ | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | | |
| | 1 | 6884438 | | 2005-04-26 | Quintanar et al. | | | |
| | 2 | 6074986 | | 2000-06-13 | Mulqueen et al. | | | |
| | 3 | 4348385 | | 1982-09-07 | Synek | | | |
| | 4 | 4610868 | | 1986-09-09 | Fountain et al. | | | |
| | 5 | 4826689 | | 1989-05-02 | Violanto et al. | | | |
| | 6 | 4997454 | | 1991-03-05 | Violanto et al. | | | |
| | 7 | 5118528 | | 1992-06-02 | Fessi et al. | | | |
| | 8 | 5145648 | | 1992-09-08 | Miyahara et al. | | | |

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|------------------------|--------|---------------------------|--|--|
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| Art Unit | | 1624 | | |
| Examiner Name Zacha | | ary C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| 9 | 5145684 | 1992-09-08 | Liversidge et al. | |
|----|---------|------------|--------------------|--|
| 10 | 5468604 | 1995-11-21 | Zengerle et al. | |
| 11 | 5665331 | 1997-09-09 | Bagchi et al. | |
| 12 | 5780062 | 1998-07-14 | Frank et al. | |
| 13 | 5858410 | 1999-01-12 | Muller et al. | |
| 14 | 5843465 | 1998-12-01 | Lundquist | |
| 15 | 5932245 | 1999-08-03 | Wunderlich et al. | |
| 16 | 6048550 | 2000-04-11 | Chan et al. | |
| 17 | 5314506 | 1994-05-24 | Midler, Jr. et al. | |
| 18 | 5624941 | 1997-04-29 | Barth et al. | |
| 19 | 6383471 | 2002-05-07 | Chen et al. | |

| Application Number | | 10561033 | | |
|-----------------------------|--|---------------------------|--|--|
| Filing Date | | 2005-12-16 | | |
| First Named Inventor Leifen | | g Cheng | | |
| Art Unit | | 1624 | | |
| Examiner Name Zacha | | ary C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| | 20 | 6432984 | | 2002-08-13 | Barth et al. | |
|----------------------|------------|--------------------------|---------------------------|---------------------|---|--|
| | 21 | 6645985 | | 2003-11-11 | Barth et al. | |
| | 22 | 6375986 | | 2002-04-23 | Ryde et al. | |
| | 23 | 6127520 | | 2000-10-03 | Ueda et al. | |
| | 24 | 5100591 | | 1992-03-31 | Cerfontaine et al. | |
| | 25 | 7342019 | | 2008-03-11 | Berggren et al. | |
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| Examiner Initial* | Cite No | Publication Number | Kind Code ¹ | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
| | 1 | 20050009908 | | 2005-01-13 | Hedberg et al. | |
| | 2 | 20060141043 | | 2006-06-29 | Lindfors | |
| | 3 | 20060198893 | | 2006-09-07 | Lindfors | |

| Application Number | | 10561033 | | |
|------------------------|--------|---------------------------|--|--|
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| First Named Inventor | Leifer | ng Cheng | | |
| Art Unit | | 1624 | | |
| Examiner Name | Zacha | ary C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| | | T | | , | | | | | | |
|----------------------|------------|---|------------------------------|------------|---------------------------|---------------------|---|---------|--|----|
| | 4 | 20050202092 | | 2005-09 |)-15 | Skantze et al. | | | | |
| | 5 | 20020188007 | | 2002-12 | ?-12 | Barth et al. | | | | |
| | 6 | 20030059472 | | 2003-03-27 | | Brynjelsen et al. | | | | |
| | 7 | 20040039024 | | 2004-02-26 | | Barth et al. | | | | |
| | 8 | 20070093484 | | 2007-04-26 | | Cheng | | | | |
| | 9 | 20060134146 | | 2006-06-22 | | Lindfors | | | | |
| If you wis | h to a | dd additional U.S. Publi | shed Ap | plication | citation | n information p | lease click the Ad | d butto | on. Add | |
| | | | | FOREIG | SN PAT | ENT DOCUM | ENTS | | Remove | |
| Examiner Initial* | Cite No | Foreign Document Number ³ | Country Code ² | | Kind Code ⁴ | Publication Date | Name of Patentee or Applicant of cited Document | | Pages,Columns,Line where Relevant Passages or Releva Figures Appear | T5 |
| | 1 | 9635414 | WO | | | 1996-11-14 | CIBA-Geigy AG | | | |
| | 2 | 9711686 | WO | WO | | 1997-04-03 | Nanosystems LLC | | | |
| | 3 | 9807414 | WO | | | 1998-02-26 | Research Triangle Pharmaceuticals Lt | td. | | |

| Application Number | | 10561033 | | |
|------------------------|--------|---------------------------|--|--|
| Filing Date | | 2005-12-16 | | |
| First Named Inventor | Leifer | g Cheng | | |
| Art Unit | | 1624 | | |
| Examiner Name Zacha | | ary C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| 4 | 9704756 | WO | 1997-02-13 | Nanosystems LLC | |
|----|----------|----|------------|---------------------------------------|--|
| 5 | 9624340 | wo | 1996-08-15 | Nanosystems LLC | |
| 6 | 0033820 | WO | 2000-06-15 | BASF Aktiengesellschaft | |
| 7 | 9713503 | wo | 1997-04-17 | The Penn State Research Foundation | |
| 8 | 9218105 | WO | 1992-10-29 | Sandoz Ltd. | |
| 9 | 0071079 | WO | 2000-11-30 | American Bioscience, Inc. | |
| 10 | 9900113 | wo | 1999-01-07 | Vivorx Pharmaceuticals, Inc. | |
| 11 | 03188438 | JP | 1991-08-16 | Fuji Photo Film Co Ltd. | |
| 12 | 589838 | EP | 1994-03-30 | CIBA-Geigy AG | |
| 13 | 9904766 | WO | 1999-02-04 | Universite Claude Bernard Lyon I | |
| 14 | 9632095 | WO | 1996-10-17 | Astra Aktiebolag | |

| Application Number | | 10561033 | | |
|------------------------|--------|---------------------------|--|--|
| Filing Date | | 2005-12-16 | | |
| First Named Inventor | Leifer | ng Cheng | | |
| Art Unit | | 1624 | | |
| Examiner Name | Zacha | ary C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| | 15 | 9814174 | wo | 1998-04-09 | Vivorx Pharmaceuticals, Inc. | |
|---|----|----------|----|------------|---------------------------------|--|
| | 16 | 9823350 | wo | 1998-06-04 | Zeneca Limited | |
| | 17 | 9959709 | wo | 1999-11-25 | Zeneca Limited | |
| | 18 | 0038811 | wo | 2000-07-06 | Glaxo Group Limited | |
| | 19 | 0044468 | wo | 2000-08-03 | Bristol-Myers Squibb Company | |
| | 20 | 0170700 | wo | 2001-09-27 | Solvay Pharmaceuticals B.V. | |
| | 21 | 0192293 | wo | 2001-12-06 | Universiteit Leiden | |
| | 22 | 0200199 | wo | 2002-01-03 | Glaxo Group Limited | |
| | 23 | 03035035 | wo | 2003-05-01 | Glaxo Group Limited | |
| | 24 | 03013472 | wo | 2003-02-20 | AstraZeneca AB | |
| | 25 | 2736230 | DE | 1978-02-16 | Nippon Soda Co., Ltd. | |
| _ | | | | | | |

| Application Number | | 10561033 | | |
|------------------------|--------|---------------------------|--|--|
| Filing Date | | 2005-12-16 | | |
| First Named Inventor | Leifer | ng Cheng | | |
| Art Unit | | 1624 | | |
| Examiner Name | Zacha | ary C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| | 26 | 275607 | EP | | 1988-07-27 | Nobel Kemi AB | | |
|-----------------------|------------|--------------------------|---------------------|----------|--------------------|--|--------|------------|
| | 27 | 2276567 | GB | | 1994-05-10 | United Kingdom Atomic Energy Authority | | |
| | 28 | 02055059 | wo | | 2002-07-18 | Baxter International Inc. | | |
| | 29 | 0377457 | EP | | 1990-07-11 | Fujisawa Pharmaceutical Co., Ltd. | | |
| | 30 | 0656354 | EP | | 1995-06-07 | Sanofi | | |
| | 31 | 0397859 | EP | | 1990-11-22 | Terumo Kabushiki Kaisha | | |
| | 32 | 458361 | СН | | 1968-06-30 | Eprova Ltd. | | |
| | 33 | 8904308 | WO | | 1989-05-18 | Terumo Kabushiki Kaisha | | |
| If you wis | h to ac | dd additional Foreign Pa | atent Document | citation | information pl | ease click the Add buttor | Add | |
| | | | NON-PATEN | NT LITE | RATURE DO | CUMENTS | Remove | |
| Examiner Initials* | Cite No | | nal, serial, symp | osium, | catalog, etc), c | the article (when appropi date, pages(s), volume-is | | T 5 |
| | 1 | Final Rejection dated Ma | arch 26, 2008 cited | d in Cop | ending Application | on No. 10/486,211. | | |

(Not for submission under 37 CFR 1.99)

| Application Number | | 10561033 | | |
|-----------------------------|--|---------------------------|--|--|
| Filing Date | | 2005-12-16 | | |
| First Named Inventor Leifen | | ng Cheng | | |
| Art Unit | | 1624 | | |
| Examiner Name Zacha | | rry C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| 2 | Non-final Office Action dated July 26, 2007 cited in Copending Application No. 10/486,211. | |
|----|--|--|
| 3 | Welin-Berger et al., "Inhibition of Ostwald ripening in local anesthetic emulsions by using hydrophobic excipients in the disperse phase," Int J Pharmaceut (2000) 200(2):249-260. | |
| 4 | Ostwald, "[Uber die vermeintliche Isomeric des roten und gelben Quecksilberoxyds und die Oberflachenspannung gester Korper,]" Phys. Chem (1900) 34:495-503. | |
| 5 | Higuchi et al., "Physical degradation of emulsions via the molecular diffusion route and the possible prevention thereof," J Pharm Sci (1962) 51:459-466. | |
| 6 | Kabalnov et al., "Ostwald ripening in two-component disperse phase systems: application to emulsion stability," Colloids and Surface (1987) 24:19-32. | |
| 7 | Lannibois et al., "Surfactant limited aggregation of hydrophobic molecules in water," Journal Phys II France (1997) 7:319-342. | |
| 8 | Lowe "Second-generation perfluorocarbon emulsion blood substitutes," Artificial Cell Blood Substitutes and Immob Biotech (2000) 28(1):25-38. | |
| 9 | Harding "The influence of lodide content on the ripening behavior of a model emulsion system," Photographic Science Engineering (1980) 24(1):32-44. | |
| 10 | Steffens et al., "O/W Emulsions as Vehicles for Micronized Drug Particles," Eur J Pharm, Biopharm (1991) 37 (4):219-226. | |
| 11 | Ruch et al., "Preparation of Micrometer Size Budesonide Particles by Precipitation," Journal of Colloid and Interface Science (2000) 229(1):207-211. | |
| 12 | Malcolmson et al., "Effect of oil on the level of solubilization of testosterone propionate into nonionic oil-in-water microemulsions," J Pharm Sci (1998) 87(1):109-116. | |

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.W./

| Application Number | | 10561033 | | |
|-----------------------------|--|---------------------------|--|--|
| Filing Date | | 2005-12-16 | | |
| First Named Inventor Leifen | | ng Cheng | | |
| Art Unit | | 1624 | | |
| Examiner Name Zacha | | ary C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| 13 | Sjostrom et al., "The formation of submicron organic particles by precipitation in an emulsion," J Dispersion Science and Tech. (1994) 15(1):89-117. | |
|----|--|--|
| 14 | Sjostrom et al., "A method for the preparation of submicron particles of sparingly water-soluble drugs by precipitation in oil-in-water emulsions. II: influence of the emulsifier, the solvent, and the drug substance," J Pharm Sci (1993) 82 (6):584-589. | |
| 15 | Kasai et al., "Crystal growth of perylene microcrystals in the reprecipitation method," Bull Chem Soc Jpn (1998) 71:2597-2601. | |
| 16 | Kasai et al., "A novel preparation method of organic microcrystals," Jpn J Appl Phys (1992) 31:L1132-1134. | |
| 17 | Mohwald et al., "Imaging and other techniques," Current Opinion in Colloid and Interface Science (1997) 2:129-130. | |
| 18 | Goddard, "Polymer-surfactant interaction Part I. Uncharged water-soluble polymers and charged surfactants," Colloids and Surfaces (1986) 19:255-300. | |
| 19 | Scalzo et al., Farmaco, Societa Chimica Italiana (1988) 43(9):677-691. | |
| 20 | Taylor et al., "Pteridines. X New Approach to the Synthesis of Pteridines," Journal of American Chemical Socity (1953) 75:1904-1908. | |
| 21 | Boon et al., "Pteridines. Part V. Derivatives of 1:4-Dihydro-1-and 3:4-Dihydro-3-methyl-6:7-diphenylpteridine," J of Chemical Society (1957) 2159-2161. | |
| 22 | Al-Dabbagh et al., "Species differences in oxidative drug metabolism: some basic considerations," Archives of toxicology, Supplement Archiv fur Toxikologie. (1984) supplement 7:219-231. | |
| 23 | Bundgaard, Design of Prodrugs, page 1, copyright 1985, Elsevier Science Publishers. | |

| Application Number | | 10561033 | | |
|-----------------------------|--|---------------------------|--|--|
| Filing Date | | 2005-12-16 | | |
| First Named Inventor Leifen | | ng Cheng | | |
| Art Unit | | 1624 | | |
| Examiner Name Zacha | | ary C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| 24 | Silverman, The Organic Chemistry of Drug Design and Drug Action (1992) Academic Press, Inc. pp. 356-400. | |
|----|--|--|
| 25 | Saikachi et al., "Synthesis of 2,3-bis (5-nitro-2-furyl) Pyrazine Derivatives," Yakugaku Zasshi (1966) 86(10):927-932 ENGLISH TRANSLATION. | |
| 26 | Notice of copending applications. | |
| 27 | Gavezzotti "Are Chrystal Structures Predictable?" Acc Chem Res (1994) 27:309-314. | |
| 28 | Martin "Frozen Transition States: Pentavalent Carbon et al," Science (1983) 221(4610):509-514. | |
| 29 | Brittain "X-Ray Powder Diffraction of Pharmaceutical Materials," American Pharmaceutical Review (2002) 5(1)74-80. | |
| 30 | Di Marzo et al., "Leptin-regulated endocannabinoids are involved in maintaining food intake," Nature (2001) 410:822-825. | |
| 31 | Howlett et al., "Azido- and isothiocyanato-substituted aryl pyrazoles bind covalently to the CB1 cannabinoid receptor and impair signal transduction," Journal of Neurochemistry (2000) 74(5):2174-2181. | |
| 32 | Office action dated May 4, 2007 received in copending application no. 10/543,264. (133087.10201) | |
| 33 | Notice of allowance dated February 8, 2008 received in copending application no. 10/543,264. (133087.10201) | |
| 34 | Office action dated March 8, 2007 received in copending application no. 10/499,054. (133087.08101) | |

| Application Number | | 10561033 | | |
|-----------------------------|-------|---------------------------|--|--|
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| Art Unit | | 1624 | | |
| Examiner Name | Zacha | ary C. Tucker | | |
| Attorney Docket Number | | 133087.09601 101119-1P US | | |

| | 35 | Notice of allowance dated January 15, 2008 received in copending application no. 10/499,054. (133087.08101) | | | | | | | | | | |
|--|---------|---|---|-------------|--------------|--------------------|----------------------|--------|-----|--|--|--|
| | 36 | Notice of allowance dated May 1, 2008 received in copending application no. 10/561,060. (133087.09401) | | | | | | | | | | |
| | 37 | Office . | Office Action dated January 7, 2008 received in copending application no. 10/561,060. (133087.09401) | | | | | | | | | |
| | 38 | Notice | Notice of allowance dated June 9, 2008 received in copending application no. 10/560,862. (133087.09301) | | | | | | | | | |
| | 39 | Office Action dated January 31, 2008 received in copending application no. 10/560,862. (133087.09301) | | | | | | | | | | |
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